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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,032	01/21/2005	Hiroaki Kambayashi	009682-142	1529

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BUCHANAN, INGERSOLL & ROONEY PC  
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ALEXANDRIA, VA 22313-1404

EXAMINER
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HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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08/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/522,032

Applicant(s)

KAMBAYASHI ET AL.

Examiner

Michael C. Henry

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____.  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/21/05,  
3/31/05,08/04/05,01/27/06.

**DETAILED ACTION**

Claims 1-8 are pending in application

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

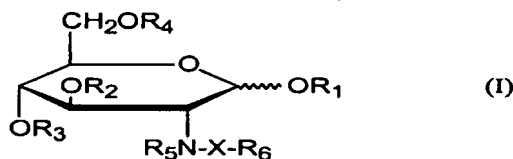
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Fieser et al.

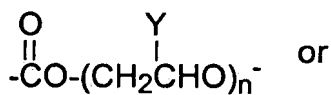
(Journal of the American Chemical Society (1956), 78, 2825-32 (Abstract Only)).

In claim 1, applicant claims an external preparation composition comprising at least one of acyl glucosamine derivatives represented by the following Formula (I):

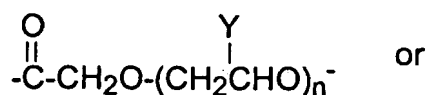


wherein  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  represent a hydrogen atom, a saturated or unsaturated, linear or branched fatty acid residue having 2 to 36 carbon atoms or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group, and they may be the same or different each other;  $R_5$  represents a hydrogen atom or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group; X is any one of groups represented by the following Formulas (A) to (C):

(A)



(B)



(C)



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wherein Y in (A) and (B) represents a hydrogen atom or an alkyl group having 1 to 5 carbon atoms in which an ether group may be interposed into a bond; and n represents an integer of 0 to 10; and R<sub>6</sub> represents a linear or branched alkyl group or alkenyl group having 11 to 36 carbon atoms which may have a substituent. Fieser et al. disclose applicant's composition of an acyl glucosamine derivative (glucosamine, N-stearoyl- or N-stearylgluconamide) represented by the following Formula (I): wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> represent a hydrogen atom; R<sub>5</sub> represents a hydrogen atom; X is represented by the following Formula (C):  $\begin{array}{c} \text{O} \\ \parallel \\ \text{-C-} \end{array}$  and R<sub>6</sub> represents a linear alkyl group having 17 carbon atoms (see abstract). Furthermore, Fieser et al. disclose that the agents or compositions which include glucosamine, N-stearoyl- or N-stearylgluconamide are emulsifying agents (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for external use or an external preparation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

In claim 2, applicant claims the external preparation composition as described in claim 1, wherein it is used as at least one of a wrinkle-improving agent, a coarse texture-improving agent, a skin roughness-improving agent a whitening agent and a acne-improving agent. Fieser et al. disclose applicant's composition of an acyl glucosamine derivative (glucosamine, N-stearoyl- or N-stearylgluconamide) represented by the following Formula (I): wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> represent a hydrogen atom; R<sub>5</sub> represents a hydrogen atom; X is represented by the following Formula (C):  $\begin{array}{c} \text{O} \\ \parallel \\ \text{-C-} \end{array}$  and R<sub>6</sub> represents a linear alkyl group having 17 carbon atoms (see abstract). Furthermore, Fieser et al. disclose that the agents or compositions which include glucosamine,

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N-stearoyl- or N-stearylgluconamide are emulsifying agents (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., wrinkle-improving agent or acne-improving agent, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

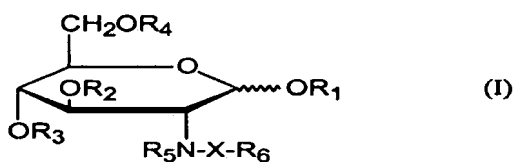
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

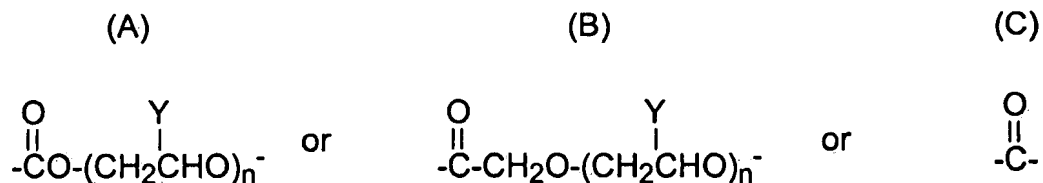
Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fieser et al. (Journal of the American Chemical Society (1956), 78, 2825-32)

In claim 1, applicant claims an external preparation composition comprising at least one of acyl glucosamine derivatives represented by the following Formula (I):



wherein  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  represent a hydrogen atom, a saturated or unsaturated, linear or branched fatty acid residue having 2 to 36 carbon atoms or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group, and they may be the same or different each other;  $R_5$  represents a hydrogen atom or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group; X is any one of groups represented by the following Formulas (A) to (C):

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wherein Y in (A) and (B) represents a hydrogen atom or an alkyl group having 1 to 5 carbon atoms in which an ether group may be interposed into a bond; and n represents an integer of 0 to 10; and R<sub>6</sub> represents a linear or branched alkyl group or alkenyl group having 11 to 36 carbon atoms which may have a substituent. In claim 2, applicant claims the external preparation composition as described in claim 1, wherein it is used as at least one of a wrinkle-improving agent, a coarse texture-improving agent, a skin roughness-improving agent a whitening agent and a acne-improving agent. Claims 3-8 are drawn to said external preparation or composition comprising specific absorption accelerator and/or chemically active substance having skin care effect, said composition further comprising a silicone oil and a silicone derivative,

Fieser et al. disclose applicant's composition of an acyl glucosamine derivative (glucosamine, N-stearoyl- or N-stearylgluconamide) represented by the following Formula (I): wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> represent a hydrogen atom; R<sub>5</sub> represents a hydrogen atom; X is represented by the following Formula (C):  $\text{-}\overset{\text{O}}{\parallel}\text{C-}$  and R<sub>6</sub> represents a linear alkyl group having 17 carbon atoms (see abstract). Furthermore, Fieser et al. disclose that the agents or compositions which include glucosamine, N-stearoyl- or N-stearylgluconamide are emulsifying agents (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for external use or an external preparation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

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The difference between applicant's composition and the composition of Fieser et al. is that Fieser et al.'s composition do not contain skin care active substance and silicon oil or silicone derivatives. However, one would be motivated to combine Fieser et al.'s emulsifying agent with other emulsifying agents or emulsifiers such as silicone oil or silicon oil derivatives and skin care active substance in order to use them in pharmacy to prepare emulsions such as creams and lotions for topical application to the skin.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Fieser et al., to prepare a composition comprising a combination of Fieser et al.'s emulsifying agent (glucosamine, N-stearoyl- or N-stearylgluconamide) with other emulsifying agents or emulsifiers such as silicone oil or silicon oil derivatives and skin care active substance, since the combination of compounds that are used to treat the same condition or with the same utility are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Fieser et al., to prepare a composition comprising a combination of Fieser et al.'s emulsifying agent (glucosamine, N-stearoyl- or N-stearylgluconamide) with other emulsifying agents or emulsifiers such as silicone oil or silicon oil derivatives and skin care active substance in order to use them in pharmacy to prepare emulsions such as creams and lotions for topical application to the skin, based on need, like the type of cream or lotion desired and the type and/or condition of skin to be treated.




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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

  
Shaojia Anna Jiang, Ph.D.  
Supervisory Patent Examiner  
Art Unit 1623

June 9, 2006.